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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,754	12/05/2003	Gregory J. Bakos	END-5244	3187
27777	7590	02/28/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			FOREMAN, JONATHAN M	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/729,754	<b>Applicant(s)</b> BAKOS ET AL.	
	<b>Examiner</b> Jonathan ML Foreman	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.  
4a) Of the above claim(s) 21-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/29/05</u> . | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1 - 20, drawn to a guide wire, classified in class 600, subclass 585.
  - II. Claims 21 - 23, drawn to a method of using a guide wire, classified in class 604, subclass 164.13.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be delivered by itself into a body without being introduced into a channel of a medical device.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
5. During a telephone conversation with Gerry Gressel on 2/2/06 a provisional election was made with traverse to prosecute the invention of Invention I, claims 1 - 20. Affirmation of this election must be made by applicant in replying to this Office action. Claims 21 - 23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Information Disclosure Statement***

The information disclosure statement filed 3/29/05 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1 – 3, 5 – 8, 12, 13 and 15 – 20 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,725,534 to Rasmussen.

In regards to claims 1 – 3, 5 – 8, 12, 13 and 15 – 20, Rasmussen discloses a guide wire structure (Figure 5) including a first segment (5) of a generally constant diameter; a second segment of generally constant diameter (13); a third segment (15) having a bending moment of inertia less than a bending moment of inertia of the first a segment and the second segment and a generally constant diameter (Col. 8, line 50) less than that of the first and second segment diameters; a tapered segment (16, 17) of decreasing diameter extending from the first segment to the third segment; and a tapered segment of decreasing diameter extending from the second segment to the third segment.

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At least one of the first, second, and third segments has a circular cross-section. Rasmussen discloses forming the wire of nitinol (Col. 6, line 66). Rasmussen discloses a visual indicator including a marking associated with one of the segments (Col. 9, line 41). The combined length of the first segment, the second segment, and the third segment is between about 7 feet and about 25 feet (Col. 6, line 66). The first segment has a length of at least about 6 feet and a generally circular cross-section having a diameter of between about 0.011 inch to about 0.035 inch (Col. 7, line 2). Rasmussen discloses the third segment having a diameter of between about 0.005 inch and about 0.010 inch (Col. 7, line 51). In use the third segment is bent while advancing within a patient and provides an elastic hinge.

9. Claims 1 – 4, 6 – 13, 15 and 18 – 20 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,87,279 to Viera.

In regards to claims 1 – 4, 6 – 13, 15 and 18 – 20, Viera discloses a guide wire structure including a first segment (40, 52, 62) of a generally constant diameter; a second segment (65) of generally constant diameter (Col. 4, lines 20 – 21); a third segment (64) having a bending moment of inertia less than a bending moment of inertia of the first a segment and the second segment and a generally constant diameter less than that of the first and second segment diameters; a tapered segment of decreasing diameter extending from the first segment to the third segment (Col. 3, lines 52 – 53); and a tapered segment of decreasing diameter extending from the second segment to the third segment (Col. 4, lines 20 – 21). Viera discloses at least one of the first, second, and third segments having a circular cross-section (Col. 4, line 20) or a non-circular cross-section (Col. 4, lines 4 – 9). Viera discloses a visual indicator (102, 103) including a marking associated with one of the segments. Viera discloses a sleeve (102) encircling the first segment (62) and a sleeve encircling the second segment (65), wherein the sleeves are visually distinguishable. The combined length of the

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first segment, the second segment, and the third segment is between about 7 feet and about 25 feet (Col. 3, line 44). The first segment has a length of at least about 6 feet (Col. 3, line 43) and a generally circular cross-section having a diameter of between about 0.011 inch to about 0.035 inch (Col. 3, line 37). In use the third segment is bent while advancing within a patient and provides an elastic hinge.

10. Claims 1 – 3, 5 – 8, 12, 13, 15 and 18 – 20 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,290,656 to Boyle et al.

In regards to claims 1 – 3, 5 – 8, 12, 13, 15 and 18 – 20, Boyle et al. discloses a guide wire structure (Figure 3) formed of nitinol (Col. 9, line 60) including a first segment (15) of a generally constant diameter; a second segment (15) of generally constant diameter; a third segment (31) having a bending moment of inertia less than a bending moment of inertia of the first a segment and the second segment and a generally constant diameter less than that of the first and second segment diameters (Col. 6, lines 14 – 33); a tapered segment (32) of decreasing diameter extending from the first segment to the third segment; and a tapered segment (33) of decreasing diameter extending from the second segment to the third segment. Boyle et al. discloses at least one of the first, second, and third segments having a circular cross-section. Boyle et al. discloses a visual indicator including a marking associated with one of the segments (Col. 3, lines 43 – 46). The combined length of the first segment, the second segment, and the third segment is between about 7 feet and about 25 feet (Col. 9, lines 55 – 58). The first segment has a length of at least about 6 feet and a generally circular cross-section having a diameter of between about 0.011 inch to about 0.035 inch (Col. 10, lines 16 – 17). In use the third segment is bent (Col. 7, lines 14 – 15) and provides an elastic hinge.

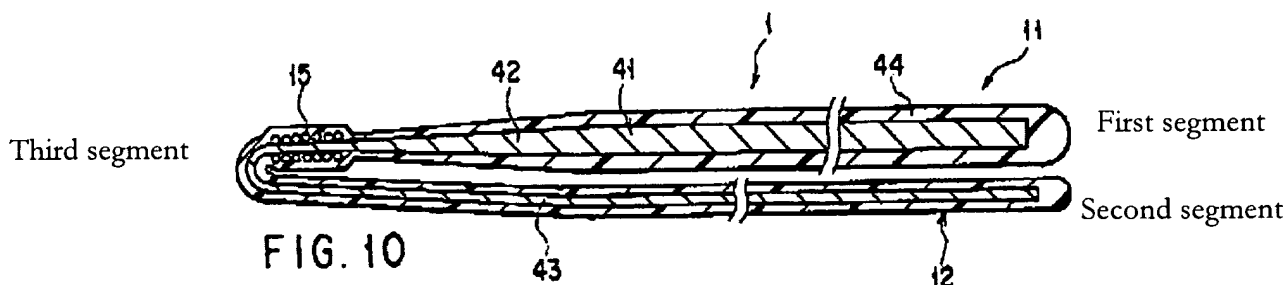
***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1 – 10, 12 - 15 and 18 – 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Application No. 2002/0087100 to Onuki et al. in view of US Patent No. 5,389,073 to Imran.

In regards to claims 1 – 10, 12 - 15 and 18 – 19, Onuki et al. discloses a guide wire structure (Figure 10) formed including a unitary wire (41) having a first segment, a second segment, and a third segment disposed intermediate the first and second segments.



Onuki et al. discloses at least one of the first, second, and third segments having a circular cross-section or a non-circular cross-section [0118]. Onuki et al. discloses a visual indicator including a marking associated with one of the segments [0109]. Onuki et al. discloses a sleeve (44) encircling each of the first and second segments. The combined length of the first segment, the second segment, and the third segment is between about 20 feet [0127][0111]. The first segment has a length of at least about 6 feet and a generally circular cross-section having a diameter of between

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about 0.011 inch to about 0.035 inch [0111]. In use the third segment is bent and provides an elastic hinge. Onuki et al. fails to disclose the third segment having a bending moment of inertia less than a bending moment of inertia of the first or second segment. However, Imran discloses a guide wire structure (Figure 6) including first segment (121), a second segment, and a third segment (126) disposed intermediate the first and second segments, wherein the third segment having a bending moment of inertia less than a bending moment of inertia of the first or second segment (Col. 4, lines 64 – 67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the third segment as disclosed by Onuki et al. to have a bending moment of inertia less than a bending moment of inertia of the first or second segment as taught by Imran to ensure that the guide wire bends at the desired position (Col. 5, lines 1 – 5).

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.




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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JMLF



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